SEP GUIDE TABLE OF CONTENTS

| Chapter | | Page |
|------------|--|-----------|
| 1. | Introduction | 2 |
| 2. | Special Emphasis Panel Process Timetable | 4 |
| 3. | Meeting Arrangements | 7 |
| 4. | Communication with Potential Reviewers | 8 |
| 5. | Member Selection | 10 |
| 6. | Appointment of Members | 11 |
| 7. | Tips for Expediting the SEP Process | 12 |
| 8. | Composition of Panel | 13 |
| 9. | Appointment Memo | 14 |
| 10. | Geographic Distribution | 19 |
| 11. | Amended Appointment Memo | 20 |
| 12. | Department Waivers –Same City/Same Organization | 24 |
| 13. | Department Waivers – Concurrent Service | 27 |
| 14. | Determination to Close | 29 |
| 15. | Notice of Meetings/Federal Register Notice | 33 |
| 16. | Roles and Responsibilities | 38 |
| 17. | Sign-in Sheet | 40 |
| 18. | Roster | 41 |
| 19. | Panel Meeting Minutes | 42 |
| 20. | Member Compensation | 43 |
| 21. | Compensation Report | 44 |
| 22. | Official File | 46 |
| 23. | Charter | 47 |
| 24 | Important Links | 49 |

1 - INTRODUCTION TO SPECIAL EMPHASIS PANELS

The Special Emphasis Panel at CDC/ATSDR

The increased number of assistance awards from CDC/ATSDR and liberalized eligibility criteria has resulted in a dramatic increase in the number of competitive applications. Subsequently, CDC and ATSDR are under increased scrutiny from applicant organizations, their supporters, and other interested parties. Among health department applicants there is greater competition for available resources, as the emphasis on application quality (a major factor in determination of awards funding) increases.

When is the SEP Process Required?

In order to determine whether or not the Grant, Cooperative Agreement, or Contract Request for Proposal falls under the SEP process, or if the assignment of a SEP is questioned, you will need to contact your Grants Management Specialist in the Procurement and Grants Office (PGO). For all other questions please contact the Federal Advisory Committee Management Team, 404-498-0090.

Special Emphasis Panel

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP) provides the most practical and objective method of application review by including federal and private sector experts. The integrity of the review process, the ability to award and process grants in a timely manner and CDC's* responsiveness to applicants is facilitated by the panel. The SEP enables expert review of assistance applications, and provides non-federal members a role in the decision-making process. Requirements for SEP composition ensure a balance of representation, providing additional objectivity to the process. All CDC programs which award grants or enter into cooperative agreements may use this Panel for the review of applications.

SEP Membership

There are no standing or appointed members of the SEP, and regulations prohibit establishment of subcommittees to the SEP. The SEP has a fluid membership, with members designated to serve for individual meetings rather than being formally appointed for fixed terms of service. Individuals designated to serve for a specific review meeting will be, upon active participation, members of the SEP for that meeting only. Thus, SEP membership changes with each meeting, and several meetings may convene concurrently.

The SEP is not considered a substitute for chartered committees with appointed members serving fixed terms.

Federal Advisory Committee Act

CDC has chartered the Special Emphasis Panel in accordance with the **Federal Advisory Committee Act** (FACA). http://intranet.cdc.gov/maso/cmppa/pdfs/faca.pdf CDC's Federal Advisory Committee Management Team (FACMT) tracks its membership and provides recurring and special reports to the Department. FACA also requires publication of a Notice of Meeting in the Federal Register at least 15 days before each SEP meeting, and compilation of minutes for each SEP meeting.

SEP Charter Renewal

The Disease, Disability and Injury Prevention and Control Special Emphasis Panel's initial charter was prepared by CDC and signed by the Secretary, HHS, on September 18, 1994. Approximate annual costs and an estimated number of reviewers was included, as well as a standard Financial Operating Plan. The charter will be forwarded to the Director, MASO (authority to sign delegated by the Secretary) by the Federal Advisory Committee Management Team, for renewal at appropriate two-year intervals. The current charter terminates September 18, 2006.

^{*}References to CDC also apply to ATSDR

2 - SPECIAL EMPHASIS PANEL PROCESS TIMETABLE

Use this as a reference to activities, responsibility delegation and scheduling, from the prereview decision to hold a panel, through post-review activities. The timetable depicts all steps described in this Guide.

For automated Timetable see: http://intranet.cdc.gov/maso/CMPPA/SEPTIMETABLE.xls

For further information, please call the Federal Advisory Committee Management Team, MASO:

Michelle Mathieson (404.498.1522),

Brenda Shepherd (404.498.1531) or

Joseph Salter, CDC/ATSDR Committee Management Officer (404.498.0090).

| Calendar Days Until Meeting | Activity |
|-----------------------------------|---|
| | DFO*/CIO |
| | Contact FACMT as soon as it is known that a SEP will be held |
| | Determine panel size; date/time/place |
| | Submit preliminary list of panel members to FACMT |
| | • Initiate the IMPAC II process for setting up peer review meetings with ??Cheryl?? |
| 60+ Days | FACMT |
| | Review preliminary list to determine whether any potential panel members are barred from participation by the HHS Office of Research Integrity (for reasons including license revocation; program-related convictions; patient abuse convictions; controlled substance convictions; health care fraud; scientific misconduct) |
| | Determine whether Department waivers are required (concurrent service on more than one CDC/ATSDR Federal advisory committee; two individuals employed by the same organization in the same city) |
| | DFO/CIO |
| 60 Days | • Contact potential panel members to determine availability and willingness to serve, if appointed (this is not a duty of a contractor if one is used) |
| | DFO/CIO |
| 53 Days | Prepare "Request to Appoint Members" and "Professional Area Breakdown" documents (e-mails documents to FACMT for review) |
| | Submits Appointment documents in final for signature in CIO (after review by FACMT); once signed in CIO, submits original signed Appointment documents to FACMT |

| | DFO/CIO | | | | | | |
|------------|--|--|--|--|--|--|--|
| | Prepare "Request for Determination to Close a Portion of a Special Emphasis Panel," Agenda, and "Determination" documents (e-mails documents to FACMT for review). Agenda for Peer Review meetings mu be generated from IMPAC II. | | | | | | |
| 50 Days | Submit Federal Register Notice (FRN) information to FACMT | | | | | | |
| · | Submit Determination documents in final for signature in CIO (after review by FACMT); once signed in CIO, submits original signed Determination documents to FACMT | | | | | | |
| | FACMT - Route Determination documents for approvals | | | | | | |
| | Prepare FRN; holds pending approval of Determination to Close | | | | | | |
| 46 Days | OGC | | | | | | |
| 40 Days | Review Determination to Close | | | | | | |
| | ADMO | | | | | | |
| 43 Days | Approve and sign Determination to Close and return to FACMT – FACMT will notify DFO/CIO of approval | | | | | | |
| | FACMT | | | | | | |
| 41 Days | Submit Federal Register Notice with approved Determination to Close to Director, MASO for approval | | | | | | |
| | Submit Federal Register Notice to the Federal Register for publication | | | | | | |
| | Federal Register | | | | | | |
| 36-20 Days | Publish Notice of Meeting (FRN for Federal advisory committee meetings, including SEPs, may be published well in advance of the meeting, but not less than 15 days before the meeting, as required by the Federal Advisory Committee Act.) | | | | | | |
| | Director, CDC | | | | | | |
| 31 Days | Appoint panel members (not the duty of a contractor if one is used) FACMT | | | | | | |
| | Notify DFO/CIO of Appointment approval | | | | | | |
| | DFO/CIO sends first correspondence to panel members: | | | | | | |
| | Welcome/Invitation Letter | | | | | | |
| 28 Days | Conflict of Interest and Confidentiality (COI) forms (Instructs panelists to return completed Conflict of Interest forms to FACMT by fax and mail.) For Peer Review us the COI forms in IMPAC II. | | | | | | |
| | List of Applications generated by IMPAC II for peer review meetings. | | | | | | |
| | Access the AAGAM for the review panel process (see links at the end of this guide.) | | | | | | |

| | PGO |
|-------------------------------|---|
| 25 Days | Receive applications |
| 22 Days | FACMT Receive Conflict of Interest and Confidentiality documents from panelists Notify DFO by e-mail and sends copies of Conflict of Interest forms to DFO |
| 21 Days | DFO/CIO • Begin travel preparations |
| 19 Days | DFO/CIO sends second correspondence to panel members: Agenda, roster, assignment sheets (Peer review documents must be generated by IMPAC II) Logistics information for reviewers Applications |
| 17 Days | Training reviewers – suggested that a teleconference be held (more than one if panel is large, just be sure everyone receives the same information) for the reviewers (See AAGAM 2.04.104C-7) Details and level of training should be commensurate with level of reviewers. |
| MEETING | MEETING |
| 1-14 Days after meeting | Submit Compensation Report, Minutes, and Roster to FACMT (for Peer Review, these forms are located in IMPAC II) |

Rev. 10/04

^{*} References to DFOs (Designated Federal Officials) also apply to SRAs (Scientific Review Administrators)

3 - MEETING ARRANGEMENTS

Upon determining the suitability of using the SEP, the DFO* will make arrangements for the meeting:

- Meeting Place
- Dates and Times
- All travel arrangements and cost of travel are the responsibility of the DFO and CIO. (See Member Compensation)

Note: A site visit or reverse site visit may be conducted as a preliminary meeting to the SEP, to provide expert consultation or advice to the SEP (any number of the panel members may participate in site visits and reverse site visits.)

After initial arrangements are made, the DFO will forward the following documents to the FACMT according to the timetable in this Guide:

- MEMO: *Request to Appoint Members to SEP* (a Professional Area Breakdown will accompany this document).
- MEMO: *Determination to Close a Meeting and agenda* (FACMT reviews the document and forwards through the Office of General Counsel and the Associate Director for Management and Operations, CDC, for clearance and approval).
- Completed "Information to Advertise Meeting of SEP in the Federal Register" sheet (FACMT prepares the Federal Register notice, obtains appropriate approvals and signatures and forwards to the Federal Register for publication).

Rev. 9/04

^{*} The FACMT has a meeting support contract set up that may be used by the programs that are sponsoring the SEP. For Information contact the Project Officers, Michelle Mathieson, 404.498.1522 or Brenda Shepherd, 404.498-1531.

4 - COMMUNICATION WITH POTENTIAL REVIEWERS

Prior to Inviting Reviewers the DFO will:

- Pre-select and contact potential reviewers to establish availability.
- Discuss confidentiality and potential conflict of interest with potential reviewers.

The DFO should inform potential reviewers that formal appointments will be approved by the Director, CDC. (Initial contact with reviewers is not the duty of a contractor if one is used)

Following Appointment of Members and Designation of Chairperson the DFO will provide panel appointees with:

- The **list** of applications/proposals. The lists for peer reviewed applications should be generated from IMPAC II. (the applications cannot be mailed until the Appointment Memo has been approved by the Director, CDC)
- Conflict of Interest and Confidentiality Certification for Non-Federal Employees (COI) form (CDC 0.1215A), at http://intranet.cdc.gov/maso/Eforms/01215A.pdf or Conflict of Interest and Confidentiality Certification for Federal Employees (COI) form (CDC 0.1215B) at http://intraspn.cdc.gov/maso/EForms/PDF/01215B.pdf. For peer review members, COI forms must be generated from IMPAC II both pre-meeting and post-meeting.

(If conflicts are discovered concerning a grant application(s), that reviewer may not participate in the review of the application(s) in conflict. The reviewer will be disqualified from participating in the meeting if he/she has submitted an application that could be reviewed in this meeting.) When the number of applications is small (e.g., six or less), or reviewers will participate in a site visit or teleconference, the DFO may verbally describe the application(s) to be reviewed. In such cases, the DFO will:

- Provide application number, title, principal investigator's name, applicant's institution name.
- Ask potential reviewers if any real or apparent conflict of interest exists.

Written Correspondence to Appointed Reviewers

Suggested First Mailing/E-mail Checklist

The DFO will send:

- Invitation Letter (e-mail)
- A list of applications/proposals to be reviewed
- COI (Must be signed and returned before applications may be sent to the reviewer)

If no disqualifying conflict exists, appointed reviewers will:

- Fax the completed, signed COI form to the FACMT SEP Team at 404/498-0011.
- Return the original signed certification to the FACMT in the business reply envelope provided by the DFO to:

Federal Advisory Committee Management Team, MASO/Attn: SEP Team Centers for Disease Control and Prevention 1600 Clifton Rd. MS-E72 Atlanta, GA 30333

Suggested Second Mailing/E-mail Checklist

After receipt of the completed COI forms the DFO will send:

- Transmittal Letter
- Agenda, Roster, and Assignment Sheets (IMPAC II generated for peer review meetings)
- Logistics information for Reviewers
- Applications (only if the Appointment Memo has been approved by the Director, CDC)

5 - Member Selection

To the extent possible, each panel should reflect a balanced membership in geographic breakdown, and minority and gender representation.

Member affiliations should represent a balance between Public Representation (i.e., private industry employee, consultant), State/County/Local Representation, and Federal Representation. *Please verify status with potential appointees*. For example, a professor at a state university may or may not be a state employee/representative; an individual who is employed by a federally funded state, county, or local program could actually be a Federal employee. **Federal representation should be kept to a minimum, and individuals who are employed in the Division sponsoring the SEP, or in areas that work very closely with the sponsoring Division, should not be appointed to serve as reviewers.**

Determining the number of reviewers needed:

The HHS Awarding Agency Grants Administration Manual (AAGAM) Chapter 2.04.104C Transmittal No. 03.01states:

Applications that are required to undergo review must be reviewed by a minimum of three qualified reviewers, whether or not an OPDIV/awarding office assigns three individual reviewers to perform in-depth review. Per the AAGAM, two of the three reviewers will provide a written critique (see section 2.04.104C-6 for requirements concerning committee composition, selection of reviewers, and conflict of interest considerations.)

Sample formula for determining the number of reviewers necessary:

Number of applications received times three, then divided by six.

(e.g., 15 applications received X 3 = 45, divided by 6 = 7-8 panelists)

For further information regarding departmental policy you can find direction to the AAGAM at the end of this guide in the chapter named "Important Links."

The annual Committee Balance report, submitted to HHS by FACMT, includes the distribution of members by gender, minority status, geographic balance, and frequency with which members were used.

6 - APPOINTMENT OF MEMBERS

The Director, CDC, has the delegated authority to appoint members to the Special Emphasis Panel. C/I/Os are encouraged to invite individuals who have not served on a panel in a given year, however, if their expertise is required, members may serve on more than one SEP in a period of one year.

Following the guidelines for member selection

The DFO will:

- The list of potential reviewers to be sent to the FACMT for review BEFORE the Appointment Memo is prepared. For a template of the spreadsheet to be used , please call the FACMT office
- Prepare the **DRAFT** of the MEMO: Request to Appoint Members to Special Emphasis Panel—ACTION, and send it FACMT for review and approval.
- Prepare the MEMO: Request to Appoint Members to Special Emphasis Panel--Action, and secure the signature/approval of the C/I/O Director. (printed on the appropriate CDC memorandum stationery, Times New Roman font, 12 pitch)
- Submit the signed original memo and an electronic copy to the FACMT. **NOTE:** If you are sending the original document through CDC mail, please make sure you put it in a folder or between cardboard so that it will not arrive folded.

The FACMT will:

- Verify that all nominees are eligible to serve on a Federal Advisory Committee by reviewing the list of persons determined ineligible by the Office of Research Integrity.
- Review and approve the **DRAFT**.
- Forward the MEMO: Request to Appoint Members to Special Emphasis Panel -- Action for approval to the Director,
- Notify the DFO electronically immediately upon receipt of the approved MEMO so the DFO can begin to initiate communications with the appointed panel members, then send hard copy to DFO/program contact.

7 - TIPS FOR EXPEDITING THE SEP PROCESS

Below you will find some helpful hints for expediting the SEP process. The SEP team will be updating this page as necessary. If you have any questions please contact Michelle Mathieson, 404.498.1522 or Brenda Shepherd, 404.498.1531.

- 1. In order to save time, please forward electronic copies of the final draft documents Appointment Memo, Waivers, Amendments, and the Determination to Close for our review **BEFORE** you prepared final documents for signatures. This will preclude our having to return documents for revision.
- 2. In circumstances where the Racial/Ethnic and/or the Geographic breakdowns are not balanced, please provide a paragraph (on the Appointment Memo under the "Discussion" section) to justify your nominees. This is an area that is closely scrutinized and it is worthwhile to answer the question before it is asked.
- 3. Please provide <u>very clear justifications</u>, **including search methods**, when requesting waivers for either "Same City/Same Organization", or "Concurrent Service" (on another Federal Advisory Committee).
- 4. The Request for a Determination to Close MUST be reviewed by OGC and signed by the Director of MASO before the FRN can be sent to be published.
- 5. To be assured that the Federal Register Notice (FRN) is published in a timely manner (15 calendar days prior to the meeting date) you must submit your FRN billing information (CDC 0.1214) at least 30 days prior to the meeting date. From this form the FACMT will generate the FRN for your approval. The approval MUST be in this office a minimum of 21 days prior to the meeting date. **NOTE:** The FRN does not publish on Federal holidays; therefore, one day should be added to the projected timetable to allow for non-publication days.
- 6. Meeting sign-in sheets should include two columns for the names of the panel members. The first column should be filled in with the "typed" names of the members, and the second column should be left blank for the member's signatures. This will eliminate confusion as to who attended the meeting. **NOTE: A separate sign-in sheet is required for each meeting date.**

Rev. 12/2004

8 - COMPOSITION OF PANEL

"Member affiliations should represent a balance between Public Representation (i.e., private industry employee, consultant), State/County/Local Representation, and Federal Representation. Federal representation should be kept to a minimum, and individuals who are employed in the Division sponsoring the SEP, or in areas that work very closely with the sponsoring Division, should not be appointed to serve as reviewers.

To the extent possible, each panel should reflect a balanced membership in geographic breakdown, minority, and gender representation.

The GSA Final Rule Subpart B, Section 102-3.60(b)(3) states: "An agency's plan to attain fairly balanced membership...[is to] ensure that in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee. Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed." Appendix A to Subpart B of the Final Rule provides the factors that should be considered in achieving a "fairly balanced" advisory committee membership. Those factors are: "(i) the advisory committee's mission; (ii) the geographic, ethnic, social, economic, or scientific impact of the advisory committee's recommendations; (iii) the types of specific perspectives required... (iv) the need to obtain divergent points of view on the issues before the advisory committee; and (v) the relevance of State, local, or tribal governments to the development of the advisory committee's recommendations."

Furthermore, two HHS publications state that diversity factors should be considered when attempting to "fairly balance" a Federal advisory committee. First, HHS General Administration Manual Chapter 9-00-70(B)(3) states: "Department policy provides that membership will be (a) fairly balanced in terms of the points of view represented and the functions to be performed; (b) composed of as equitable geographic, ethnic and gender representation so long as the effectiveness of the committee is not impaired; (c) selected without discrimination on the basis of age, ethnicity, gender, sexual orientation, disability or cultural, religious, or socioeconomic status; and (d) appointed in such a manner as to assure an orderly rotation of the members' terms." Second, the Department Committee Management Handbook, Part III, states: "Department policy provides that committee membership will be fairly balanced in terms of points of view represented and the committee's function. Consideration will be given to a broad representation of geographic areas, females, ethnic and minority groups, and the handicapped."

The annual Committee Balance report, submitted to HHS by FACMT, includes the distribution of members by gender, minority status, geographic balance, and frequency with which members were used.

We realize that it is not always possible to achieve balance; therefore, a strong justification paragraph explaining how you went about selecting your panel and why balance was not attainable is required as part of the Appointment Memo.

9 - APPOINTMENT MEMO

The Appointment Memo is the official document, signed by the Director of CDC, formally appointing the reviewers for a one-time Special Emphasis Panel. The document MUST be printed on CDC Memorandum stationery and include the following information:

- Announcement Name and Number, and date(s) of the panel
- The Racial/Ethnic, Gender, representation, and geographic breakdown of the panel
- List of FACMT approved nominees (in alphabetical order) Proposed Chair must be identified with an *
- Authorized CIO signature and degree(s) **MUST** be original (**NOTE**: be sure the CIO Official does not sign on the "Decision" line)
- The Professional Area Breakdown List **MUST** accompany the Appointment Memo (both hard and electronic copies)

Before having the Appointment Memo signed, an electronic draft MUST be sent to the FACMT for review and approval. After the memo is signed please hand-deliver the original to the FACMT. If this is not possible make sure the memo is protected from being folded or bent when placing it in the CDC mail system. An electronic copy of the final memo MUST be sent to the FACMT at the same time.

EXAMPLE OF APPOINTMENT MEMO

(Signed version must be on official CDC Memorandum paper)

NOTE: Please forward an electronic version of the final draft to the FACMT for reviewand approval, BEFORE having it signed by the program official.

Date: (insert date sent to CIO official)

From: Director, (insert name of CIO and acronym in parentheses)

Subject: Request to Appoint Members to Special Emphasis Panel -- ACTION

To: Julie Louise Gerberding, M.D., M.P.H.

Director, Centers for Disease Control and Prevention

ISSUE

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel will hold a meeting on (insert meeting date(s)), to review, discuss, and evaluate applications received in response to Program Announcement (PA) #(insert announcement number), (insert title of meeting.) The applications being reviewed include information that requires the expert evaluation of microbiologists, immunologist, and infectious disease specialists.

DISCUSSION

(if necessary insert justification here – see example that follows) The Office of Extramural Research reviewed over 20 Schools of Medicine faculty lists, reviewed 6 Historically Black Colleges and Universities faculty listings, reviewed the MASO database, and personally contacted over 50 individuals recognized as experts in the fields of microbiology, immunology, and infectious diseases as evidenced by education, experience, and accomplishments, including publications in peer reviewed journals, to serve as Panel members.

The nominees listed below possess the necessary expertise and represent a geographic, demographic, and gender balance. If all nominees are approved, female and minority representation would be as follows: (if Racial/Ethnic, Gender, or Geographic breakdown is not balanced, you must include a paragraph to explain – see "Composition of Panel") fill in percentages as show in the example below

Female: 17% (2 out of 12 nominees) Minority: 25% (3 out of 12 nominees)

Hispanic 8% (1 out of 12 nominees)
Asian/Pacific Islander 17% (2 out of 12 nominees)
Native American 0% (0 out of 12 nominees)
Black 0% (0 out of 12 nominees)

(The total of the minority breakdown must equal the total minority percentage – in this

case

25% - avoid decimals and round off as necessary)

Public Representation: 67% (8 out of 12 nominees)
State/County/Local Representation: 25% (3 out of 12 nominees)
Federal Representation: 8% (1 out of 12 nominees)

Page 2 – Julie Louise Gerberding, M.D., M.P.H.

| Geographic Breakdo | | 100%, avoid dec | imals and rour | nd off as necessa | ary) |
|----------------------|-----------------|------------------|-----------------|-------------------|-----------|
| West: | 33% | | | | |
| Central: | 0% | | | | |
| East: | 34% | | | | |
| South: | 33% | om outside the U | C above them | os "Othor" plus | 0/) |
| (II any of the | nominees are ir | om outside the U | S, snow them | as Other plus | %) |
| <u>Panel</u> | | | | | |
| Xxxx, Abdu | | | | | |
| Xxxxxx, Jorge | | | | | |
| Xxxxxxx, Caroline | | | | | |
| Xx Xxxxx, Aravinda | a | | | | |
| Xxxxxxxxxx, Louis | | | | | |
| Xxxxxxx, Richard | | | | | |
| Xxxx, Patricia | | | | | |
| Xxxxxxx, D. Scott | | | | | |
| Xxxxx, Jonathan | | | | | |
| Xxxxxxxxx, Brian* | | | | | |
| Xxxxx, Richard | | | | | |
| Xxxxx, Stephen | | | | | |
| "*" denotes chair | | | | | |
| RECOMMENDATI | ON | | | | |
| I recommend that th | | roposed reviewer | s be formally a | ppointed to serv | ve on the |
| Disease, Disability, | - | - | • | | |
| #(insert the announc | | | 1 221 (111501) | | 8, |
| | | | | | |
| <u>DECISION</u> | | | | | |
| A | | | Data | | |
| Approved | | | _ Date | | |
| Disapproved | | | Date | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | [Anthon | izad CIO sign | ature, degree(s | 91 |
| | | [Author | izeu CIO sign | ature, uegree(s | 71 |
| Attachment: | | | | | |
| Professional Area B | reakdown | | | | |

Professional Area Breakdown:

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel Meeting

Insert meeting name and Program Announcement Number

(insert meeting date(s))

| Name | Race | Gender | Organization | Expertise | City | State |
|--|------|--------|---|--------------------------|--------------------|-------|
| Abdu Xxxx | A | M | University of Maryland | Microbiology | Baltimore | MD |
| Jorge Xxxxxx | Н | M | Stony Brook | Microbiology | Stony Brook | NY |
| Caroline Xxxxxxx | W | F | University of Washington | Infectious Disease Adult | Seattle | WA |
| Aravinda xx Xxxxx | Н | M | University of North Carolina, Chapel Hill | | Chapel Hill | NC |
| Louis Xxxxxxxxxx | W | M | Connecticut Agricultural Experiment Station | Entomology | New Haven | СТ |
| Richard Xxxxxx | W | M | Medical College of Virginia | Microbiology | Richmond | VA |
| Patricia Xxxx | W | F | Rocky Mountain Laboratories | Microbiology | Hamilton | MT |
| D. Scott Xxxxxxx | W | M | University of Montana | Microbiology | Missoula | MT |
| Jonathan Xxxxx | W | M | Texas A & M | Microbiology | College Station | TX |
| Brian Xxxxxxxx* | W | M | University of Kentucky | | | KY |
| Richard Xxxxx | W | M | Colorado State | Immunology | Ft. Collins | CO |
| Stephen Xxxxx | W | M | University of Connecticut Health Ctr. | | Farmington | CT |
| Continue listing all names, race, gender, organization, expertise, city, and state | | | | | | |

"*"Denotes chair

REFERENCE INFORMATION: ACRONYM PREFERENCE*

Racial/Ethnic/Gender codes/Geographic:

```
Race and National Origin Identification:
Asian/Pacific Islander (API)*
White (W)*
Black (B)*
Alaska Native/Native American (AN/NA)*
Hispanic (H)*
Other or Unknown (U)* **
```

Gender Identification:

F - Female*
M - Male*
U - Unknown* **

Geographic Codes:

E = EastW = West

C = Central

S = South

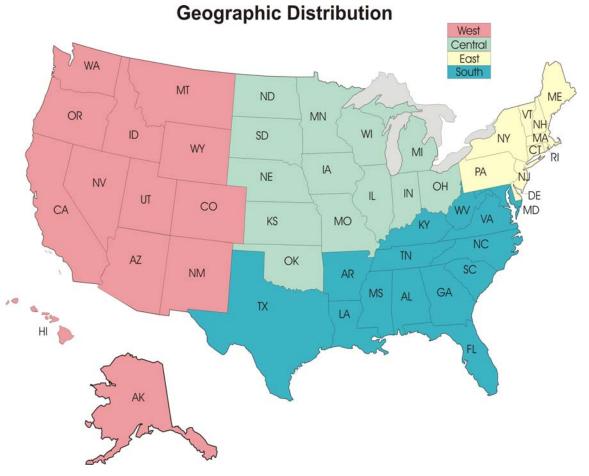
O = Other (If there are any panel members from outside the US, notate as O =other)

** Final attachment CANNOT indicate racial/ethnic or Gender as "U" – these codes can only be used on the initial list that is sent to the FACMT for review

Rev. 9/04

^{*} use alpha as indicators

10 - GEOGRAPHIC DISTRIBUTION



This map is provided for use in developing a balanced membership:

| Alabama | South | Louisiana | South | Oklahoma | Central |
|----------------|---------|----------------|---------|----------------|---------|
| Alaska | West | Maine | East | Oregon | West |
| American Samoa | West | Maryland | South | Pennsylvania | East |
| Arkansas | South | Massachusetts | East | Puerto Rico | South |
| Arizona | West | Michigan | Central | Rhode Island | East |
| California | West | Minnesota | Central | South Carolina | South |
| Colorado | West | Mississippi | South | South Dakota | Central |
| Connecticut | East | Missouri | Central | Tennessee | South |
| Delaware | East | Montana | West | Texas | South |
| Florida | South | Nebraska | Central | Utah | West |
| Georgia | South | Nevada | West | Vermont | East |
| Guam | West | New Hampshire | East | Virgin Islands | South |
| Hawaii | West | New Jersey | East | Virginia | South |
| Idaho | West | New Mexico | West | Washington | West |
| Illinois | Central | New York | East | Washington DC | South |
| Indiana | Central | North Carolina | South | West Virginia | South |
| Iowa | Central | North Dakota | Central | Wisconsin | Central |
| Kansas | Central | Ohio | Central | Wyoming | West |
| Kentucky | South | | | | |

If not from the United States or one of its territories, the distribution would be "Other." Rev. 04/02

11 - AMENDED APPOINTMENT MEMO

If it becomes necessary to appoint additional members to your panel*, an Amended Appointment Memo is required. The process is the same as for the Appointment Memo. Submit names of proposed panel members for approval. Once approval is received send the **DRAFT** electronically to MASO for review.

The memo is the same with these changes/additions:

- 1. Subject of memo will read:
 - "Amended Request to Appoint Members to a Special Emphasis Panel ACTION"
- 2. In the "Discussion" portion of the memo a paragraph must be inserted to explain and justify the amendment. An example would be:
 - "This is an amended request to appoint a new member to the SEP Panel. An existing appointee resigned due to family illness emergency and we wish to nominate a replacement. Although we submitted and you approved alternate member to this panel, this individual's expertise in a specific discipline cannot be replaced by an alternate."
- 3. Make any changes necessary to the Racial/Ethnic/Gender/Geographic Breakdown.
- 4. Attach a new List of Proposed Panel Members, and **BOLD** the name of the additional name(s).

^{*}Adding additional members may occur for several reasons e.g., more applications than expected, a member had to drop out. It is not necessary to use all of the names approved by the Director, BUT if an applicant has NOT been approved they cannot serve.

Example of Amended Appointment Memo

(Signed version must be on official CDC Memorandum paper)

NOTE: Please forward an electronic version of the final draft to the FACMT for review and approval, BEFORE having it signed by the program official.

Date: (insert date sent to CIO official)

From: Director, (insert name of CIO and acronym in parentheses)

Subject: Amendment to Request to Appoint Members to Special Emphasis

Panel -- ACTION

To: Julie Louise Gerberding, M.D., M.P.H.

Director, Centers for Disease Control and Prevention

ISSUE

This is a request to amend the membership of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP) meeting on (insert meeting date(s)), to review, discuss, and evaluate applications received in response to Program Announcement (PA) #(insert announcement number), insert name of meeting). Due to the unexpected volume of applications received, the original size of the panel is inadequate to efficiently and effectively evaluate the proposals. The proposed changes in the panel maintain the expertise required for this SEP.

DISCUSSION

The Office of Extramural Research reviewed over 20 Schools of Medicine faculty listings, reviewed six Historically Black Colleges and Universities faculty listings, reviewed the MASO database, and personally contacted over 50 individuals recognized as experts in the fields of microbiology, immunology, and infectious diseases as evidenced by education, experience, and accomplishments, including publications in peer reviewed journals, to serve as Panel members.

The nominees listed below possess the necessary expertise and represent a geographic, demographic, and gender balance. If all nominees are approved, female and minority representation would be as follows:

Female: 23% (3 out of 13 nominees) Minority: 15% (2 out of 13 nominees)

Hispanic 0% (0 out of 13 nominees)
Asian/Pacific Islander 15% (2 out of 13 nominees)
Native American 0% (0 out of 13 nominees)
Black 0% (0 out of 13 nominees)

Public Representation: 62% (8 out of 13 nominees)
State/County/Local Representation: 23% (3 out of 13 nominees)
Federal Representation: 15% (2 out of 13 nominees)

Page 2 – Julie Louise Gerberding, M.D., M.P.H.

| Geograph | ic Breakdow | n: | | | |
|------------------------|---------------------|--|--------------|------------------|---------------------|
| W | est: | 31% | | | |
| Ce | entral: | 0% | | | |
| Ea | ıst: | 31% | | | |
| Sc | outh: | 38% | | | |
| Panel: | | | | | |
| Xxxx, Ab | du | | | | |
| Xxxxxx, | | | | | |
| Xxxxxxx, | , Caroline | | | | |
| Xx Xxxxx | x, Aravinda | | | | |
| Xxxxxxx | xx, Joseph | | | | |
| Xxxxxx, | Peter | | | | |
| Xxxxxxx | xxx, Louis | | | | |
| Xxxxxxx, | , Richard | | | | |
| Xxxx, Pat | tricia | | | | |
| Xxxxxxx, | D. Scott | | | | |
| Xxxxx, Jo | | | | | |
| | xx, Brian* | | | | |
| Xxxxx, R | | | | | |
| * denotes | chair | | | | |
| I recomm Disease, I | | above list of proposed and Injury Prevention a | | | |
| <u>DECISIO</u> | <u>N</u> | | | | |
| Approved | l | | | Date | _ |
| Disapprov | ved | | | Date | |
| | | | [A ı | uthorized CIO si | gnature, degree(s)] |
| Attachme Profession | nt: nal Area Bre | akdown | | | |

Professional Area Breakdown:

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel Meeting

(Insert name of meeting and Program Announcement Number)

(Insert meeting date(s))

| Name | Race | Gender | Organization | Expertise | City | State |
|----------------------|------|--------|---|--------------------------|--------------------|-------|
| Abdu Xxxx | W | M | University of Maryland | Microbiology | Baltimore | MD |
| Sandra Xxxxxxxx | W | F | Univ. of CT | Veterinary | Storrs | CT |
| Caroline Xxxxxxx | W | F | University of Washington | Infectious Disease Adult | Seattle | WA |
| Aravinda Xx Xxxxx | A | M | University of North Carolina, Chapel Hill | Microbiology | Chapel Hill | NC |
| Joseph Xxxxxxxx | A | M | CDC | Microbiology | Atlanta | GA |
| Peter Xxxxxx | W | M | Ct. Child. Med. Ct | Infect. Dis Child | Hartford | CT |
| Louis Xxxxxxxxxx | W | M | Connecticut Agricultural Experiment Station | Entomology | New Haven | CT |
| Richard Xxxxxxx | W | M | Medical College of Virginia | Microbiology | Richmond | VA |
| Patricia Xxxx | W | F | Rocky Mountain Laboratories | Microbiology | Hamilton | MT |
| D. Scott Xxxxxxx | W | M | University of Montana | Microbiology | Missoula | MT |
| Jonathan Xxxxx | W | M | Texas A & M | Microbiology | College Station | TX |
| Brian Xxxxxxxx* | W | M | University of Kentucky | Microbiology | Lexington | KY |
| Richard Xxxxx | W | M | Colorado State | Immunology | Ft. Collins | CO |

^{*}Denotes Chair

12 - WAIVER – SAME CITY/SAME ORGANIZATION

When the FACMT reviews the list of potential reviewers to determine if they are cleared to serve they will also check to see if there are individuals on the list who are from the same organizations and working in the same city. The DFO will be advised that this check was done "based on the information at hand" and that the submitting office is responsible to check for this also. When this situation arises it is recommended that, if possible, other selections are made to avoid having to do waivers. If this is not possible the DFO will need to prepare a waiver requesting that the parties be allowed to serve even though they are from the same city/same organization.

Is a Waiver needed?

- Two or more reviewers who are working for the same organization **AND** in the same city, e.g., Johns Hopkins Hospital yes, a waiver will be needed
- Two or more reviewers who are working for the same organization **BUT NOT** in the same city, e.g., University of CA, one reviewer in Davis and one reviewer in Santa Barbara no, a waiver is not needed
- Two or more reviewers who are working for the same organization AND in the same city BUT not in the same department, e.g., Emory University, one reviewer at the Rollins School of Public Health and one reviewer at Emory Hospital no, a waiver will not be needed
- Questionable situations please contact the FACMT

Waiver requests must have an extremely strong justification in order for it to be approved. You must explain in detail how you went about searching for reviewers, what the results of your search were, and why this person's expertise is important to the SEP.

If there are more than two groups of reviewers (e.g., two from UCLA, two from Johns Hopkins, and three from the Mayo Clinic) one waiver can be done, with explanations for each group, or one waiver can be done for each group.

EXAMPLE DEPARTMENT WAIVER FOR SAME ORGANIZATION IN THE SAME CITY

(Signed version must be on official CDC Memorandum paper)

NOTE: Please forward an electronic version of the final draft to the FACMT for review and approval, BEFORE having it signed by the program official.

Date: (insert date memo is sent for signature)

From: Director, (insert name of CIO with acronym in parentheses)

Subject: Request to Waive Department Policy Regarding Two Committee Members from

the Same Organization in the Same City

To: Alvin Hall

Director, Management Analysis and Services Office (MASO)

I am requesting exceptions be made to Department Policy to allow (list names) to serve on the CDC, Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): (insert title of SEP), Program Announcement Number (PA) #(insert number). Inclusion of these (insert number of persons) persons would mean there would be (insert number of persons) persons each from (insert number of institutions) different institutions on this SEP.

An extensive search was made to obtain qualified candidates for this panel with education and expertise in rural public health, occupational safety and health in agriculture, agricultural engineering, Cooperative Extension, small minority farmers, evaluation of interventions, agricultural education, and stress and who are available and willing to dedicate time to this review. Finding qualified persons able to serve was further complicated because many of those with the expertise to serve could not because they are submitting an application themselves. The individuals discussed here have backgrounds in various areas related to the expertise needed on this panel.

** (list names)., who are proposed nominees for this panel, are from Ohio State University (OSU). (insert name) is Associate Professor in the School of Public Health and is highly recognized for her (or his) expertise in public health and in stress. (insert name) is also at Ohio State as a Professor in the School of Public Health in the Food Engineering Department with strong expertise in food safety and education.

** (List names)., who are proposed nominees for this panel, are from Alcorn State University. (insert name) is Dean of the School of Nursing and has expertise in rural health, education, and community-based agricultural health projects. (insert name) is Associate Professor of Nursing Education with expertise in food safety education and rural health.

Page 2 – Alvin Hall, Director, Management Analysis and Services Office

** (List names), who are proposed nominees for this panel, are from Colorado State University. (insert name) is in the Department of Chemical and Bio-resource Engineering. His expertise is related to tractor safety, whereas (insert name) is Director of the Director of the Center for Chemical and Bio-resource Engineering, and has expertise in injury control and evaluation.

In view of the foregoing, I request that you grant this waiver for the service of all (insert number of persons) of these individuals on the SEP to be held in response to PA #(insert number).

| [Authorized CIO signature | [Authorized CIO signature/degree(s)] | | |
|---------------------------|--------------------------------------|--|--|
| | | | |
| | | | |
| Director MASO | | | |
| | [Authorized CIO signatur | | |

** This example shows multiple waiver requests within the same request memo. It is also acceptable to submit separate requests for each organization.

13 - WAIVER – CONCURRENT SERVICE

When the FACMT reviews the list of potential reviewers to determine if they are cleared to serve they will also check to see if there are names on the list who are currently serving on a standing Federal Advisory Committee. The DFO will be advised that this check was completed and that one or more reviewers will require waivers for service on two committees concurrently. It is recommended that, if possible, other selections are made to avoid having to do waivers. If this is not possible the DFO will need to prepare a waiver requesting that the parties be allowed to serve even though they are serving on another committee.

Waiver requests must have an **extremely strong justification** in order for it to be approved. You must explain in detail how you went about searching for reviewers, what the results of your search were, and why this person's expertise is important to the SEP.

EXAMPLE DEPARTMENT WAIVER FOR SERVICE ON TWO COMMITTEES CONCURRENTLY

(Signed version must be on official CDC Memorandum paper)

NOTE: Please forward an electronic version of the final draft to the FACMT for review and approval, BEFORE having it signed by the program official.

Date: (insert date memo sent to be signed)

From: Director, (insert CIO name and acronym in parentheses)

Subject: Request for Waiver of Department Policy Regarding Service on Two Committees

Concurrently

To: Alvin Hall

Director, Management Analysis and Services Office (MASO)

I am requesting that an exception be made to Department Policy to allow (insert name(s))., to serve on the CDC Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): (insert name of panel, Program Announcement (PA) #(insert number). This panel will convene on (insert meeting date(s)). (insert name(s)) is currently serving on the (insert committee name) for a term that began (insert date), and ends (insert date).

An extensive search was made to obtain qualified candidates for this panel with education and expertise in occupational health and safety, health and cultural issues for Hispanic workers, with experience in reviewing competitive grants and who are available and willing to dedicate time to this review. (insert name) is a registered nurse and nurse practitioner with an extensive research and publication record that includes cultural and health issues related to the Hispanic community. She is currently chairperson of a department of psychiatric and community health nursing as well as acting chair for maternal & child health. This experience will be particularly valuable in reviewing the wide diversity of cooperative agreements dealing with community-based intervention research that are expected to include Hispanic workers and children.

In view of the foregoing, it is requested that you grant this waiver allowing (insert name) to be appointed to serve on the SEP to be held (insert date(s)).

| | [Authorized CIO signat | ure/degree(s)] |
|------------------------|------------------------|----------------|
| Approved: Disapproved: | Director, MASO | |

14 - DETERMINATION TO CLOSE

The Determination to Close a portion of the SEP meeting **MUST** be completed* **BEFORE** the Federal Register Notice (FRN) can be sent for publication. In order to ensure the FRN be in print for the minimum of 15 days (as required) before the SEP begins, the Determination to Close should be sent for approval as soon as the Agenda (location of meeting) is complete. Because of this requirement it is strongly recommended that the Determination to Close Memo, the Determination, and the Agenda be approved and in the FACMT at least 43 days before the meeting. Once the Determination to Close is reviewed by the OGC, and signed by the Director of MASO, the FACMT will prepare the FRN for the DFO's approval. After the FRN is signed by the Director of MASO it will be sent forward to be printed in the Federal Register.

While few FACA meetings can be closed to the public, and only when a legal determination has been made that it is necessary to close the meeting, SEPs are closed to the public. The Determination to Close is submitted because the applications being reviewed include information of a confidential nature, including personal and financial information concerning individuals associated with the applications.

* Reviewed by OGC and signed by the Director of MASO

EXAMPLE OF DETERMINATION TO CLOSE

(Signed version must be on official CDC Memorandum paper)

NOTE: Please forward an electronic version of the final draft to the FACMT for review and approval, BEFORE having it signed by the program official.

Date: (insert the date sent to CIO Official)

From: Director, (insert name of CIO and (acronym) in parentheses)

Subject: Request for Determination to Close the Meeting to Review Applications

Received in Response to Program Announcement #(insert program

announcement number)

To: Alvin Hall

Director, Management Analysis and Services Office (MASO)

ISSUE

A Special Emphasis Panel (SEP) will be held (insert meeting date(s)) to review, discuss, and evaluate applications received in response to Program Announcement (PA) #(insert announcement number), (insert name of meeting). The meeting will concern subject matter considered confidential under the terms of Section 552b(c) (4) and (6), Title 5, U.S.C., and Section 10(d) of Public Law 92-463. Accordingly, I request that this meeting be closed to the public.

DISCUSSION

The meeting will include the review, discussion, and evaluation of applications received in response to PA #(insert PA number), insert name of meeting). The applications being reviewed include information of a confidential nature, including personal and financial information concerning individuals associated with the applications.

RECOMMENDATION

I recommend that the attached Determination to Close the (insert meeting date(s)) SEP meeting be signed.

[Authorized CIO signature/degree(s)]

Attachments: Determination to Close Agenda **NOTE:** Do **NOT** change any of the information in the two paragraphs that make up the Determination. This is an official government form. Complete only the three items – date(s) of meeting, name of panel, and announcement #. If there are changes OGC will not approve the Determination to Close.

DETERMINATION

| Date(s) of Meeting: | | |
|---|--|---|
| Name of Panel: | | - |
| | | |
| Announcement #: | | - |
| Special Emphasis Panel in in response to the cited so confidential nature, include associated with the application | eeting of the Disease, Disability, and Injury Prevention and Involves the review, discussion, and evaluation of applications. The applications being reviewed include individing personal and financial information concerning individuals. For these reasons and pursuant to 5 U.S.C. Sections of the public observation and any confidential information disclosed. | ations received formation of a viduals ion 552b(c) (4) |
| effective February 8, 1995 redelegated to the Deputy redelegated to the Associared legated to the Director 28, 2002, it is hereby determined. | e delegation of authority from the Assistant Secretary for 5, to the Director, Centers for Disease Control and Prevolution of Program Management, CDC, effective January Director for Program Services, CDC, effective January, Management Analysis and Services Office, CDC, effective in accordance with the provisions of Section 10 pp. 2) that the meeting referred to above will be closed a | ention (CDC), nuary 25, 2002, ary 25, 2002, fective January (d) of Public |
| Date | Director, Management Analysis and Services Offic | _ e |

http://intraspn.cdc.gov/maso/eforms/clicktracker.aspx?id=1680

Agenda example

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel Meeting:

(Insert name of SEP), PA # (Insert Program Announcement Number)

(Insert meeting date(s))

(Hotel name)
(Hotel address)
(city/state/zip)
(area code/telephone)

AGENDA

(Date)(Closed to the Public)
(time) a.m. – (time) a.m.

(Date)(Closed to the Public)
(time) a.m. – (time) p.m.

(time) p.m.

Evaluation of Applications
Adjourn

NOTE: If the SEP is for more than one day, insert the information in the same format as the evaluation of applications portion.

15 - NOTICE OF MEETINGS – THE FEDERAL REGISTER NOTICE

Federal Register Notice

The Federal Advisory Committee Act requires publication of a Notice of Meeting in the Federal Register not less than 15 days before each SEP meeting. Clearance must be obtained at several levels in CDC before a meeting can be advertised.

The DFO will:

Submit a completed "CDC Information Sheet: Special Emphasis Panel Federal Register Notice" (CDC 0.1214) sheet to the FACMT 60 days prior to the meeting. A sample of this form can be seen below and by accessing the following link,

http://intraspn.cdc.gov/maso/eforms/clicktracker.aspx?id=339

Example of CDC Information Sheet: Special Emphasis Panel Federal Register Notice:

Centers for Disease Control and Prevention Information Sheet: Special Emphasis Panel Federal Register Notice

| (Federal Register Notice must be published not later than 15 days before the meeting. Please submit this information to FACMT not later than 30 days before the meeting.) Billing Code: |
|---|
| Name of CIO and Sponsoring Division: |
| Name of Special Emphasis Panel and Program Announcement Number: |
| Meeting Date(s): |
| Starting and ending times: |
| Location of meeting (complete address including zip code, phone number): |
| Matters to be discussed: |
| Designated Federal Official (DFO) |

Name, Title:

Mailing Address:

Phone:

E-mail Address:

CDC 0.1214 Rev. 3/01

The FACMT will:

Prepare the Federal Register notice based on the information provided by the program, send it to the Program for approval, secure required CDC approvals, and coordinate publication in the Federal Register.

(EXAMPLE OF FEDERAL REGISTER NOTICE)

(The notice is prepared by the FACMT using the information provided by the program on form 1214. It is then sent to the program, along with the electronic authorization form for their approval. Once approval is received by the FACMT it is sent for the Director of MASO's signature. Then it will send it to the Federal Register)

BILLING CODE: 4163-18-P

```
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Disease, Disability, and Injury Prevention and Control
Special Emphasis Panel (SEP): (insert name of SEP as it was
announced), Program Announcement Number (insert announcement number).
In accordance with Section 10(a)(2) of the Federal Advisory
Committee Act (Pub. L. 92-463), the Centers for Disease Control and
Prevention (CDC) announces the following meeting:
       Disease, Disability, and Injury Prevention and Control Special
NAME:
Emphasis Panel (SEP): (insert name of SEP as it was announced),
Program Announcement Number (insert announcement number).
TIMES AND DATES: time p.m.-time p.m., date (Open)
                  time a.m.-time p.m., date (Closed)
                  time a.m.-time p.m., date (Closed)
                  time a.m.-time p.m., date (Closed)
PLACE: (insert hotel information: name, address, city/state/zip,
telephone number).
```

STATUS: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

MATTERS TO BE DISCUSSED: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number (insert announcement number).

CONTACT PERSON FOR MORE INFORMATION: (insert name of DFO, SRO, or contact person, title of contact person, CIO, CDC, address, MS-XXX, city, state, zip, Telephone number.)

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated:

Alvin Hall

Director, Management Analysis and Services Office
Centers for Disease Control and Prevention

(The FRN will be prepared by FACMT Office)

FEDERAL REGISTER NOTICE AUTHORIZATION FORM

After FACMT completes the FRN, we will send it to you electronically along with the approval form as shown below. This form does not require an original signature—just type in the required information and return to the FACMT electronically. The approval of this form should be from the DFO or SRA.

FRN Approval Form:

I have read and approve the contents of the attached Federal Register notice announcing the (Insert name of meeting) on (insert date(s)). I approve the use of the following Federal Express account number: (insert FedEx account number. Please accept this e-mail as my authorization for publication.

Name: (insert name of authorized person)

Title: (insert title and CIO)
Date: (insert date approved)

This form will be sent to you, from FACMT, along with the FRN

16 - ROLES AND RESPONSIBILITIES

The Center/Institute/Office using the SEP will identify a Designated Federal Official (DFO) or Scientific Review Administrator (SRA) to assume overall responsibility for each SEP meeting. There MUST be a DFO/SRA in attendance for every panel of every SEP. As required by the Federal Advisory Committee Act (FACA), responsibilities are as follows:

Designated Federal Official (DFO)

Before the meeting:

- Approves plans to hold a review.
- Coordinates logistical arrangements for the meeting, including, when necessary, arranging for travel and overnight accommodations for panel members.
- Coordinates financial arrangements for compensation, travel and per diem of panel members.
- During Member Selection process, assures appropriate representation of women and minorities and a balanced geographic distribution among participants of individual SEP meetings.
- Coordinates submission of the following to the Federal Advisory Committee Management Team (FACMT):
 - o MEMO: Request for Determination to Close, and meeting Agenda.
 - o Federal Register Notice Information Sheet.
 - o MEMO: Request to Appoint Members to Special Emphasis Panel -- Action.
- Arranges for resource persons and supplementary materials to assist the panel members in dealing with agenda items.
- Assigns reviewers to the applications (this is NOT a duty for a contractor if one is used for meeting support)
- Reviews members' conflict of interest statements in conjunction with applications to be reviewed to determine whether any member(s) should be disqualified from reviewing a given application.
- Coordinates mailing of review documents and notification of members as to the date(s), time, and place of the review meeting.
- Arranges for a representative from PGO to attend panel meetings.

During the Review Meeting:

- Ensures the panel conducts its business in accordance with all applicable regulations, policies, and procedures.
- Adjourns the meeting when such adjournment is in the public interest or in the best interest of the government.
- Ensures that no recording are made of any part of the panel meeting

Within 14 calendar days after the Review Meeting DFO submits reports to the FACMT:

- Compensation Report including travel and per diem figures.
- Minutes of the Review certified by the Chairperson.
- A complete Roster of Members participating in the Review.

Executive Secretary (ES): The CDC/ATSDR Committee Management Officer serves in the capacity of Executive Secretary of the SEP program and ensures that the FACMT will:

- Review and secure timely approval of the Memos "Request for Determination to Close," and "Request to Appoint Members".
- Prepare and submit the Federal Register Notice in adequate time to assure publication not less than 15 calendar days prior to the Review.
- Prepare Determination to Close.
- Receive and forward copies to the DFO of all conflict of interest statements.
- Collect and compile data for the reports: "Quarterly Compensation Report," and "Quarterly Schedule of Meetings."

Additional Responsibilities of the FACMT:

- Prepare and submit the President's Annual Report on Federal Advisory Committees to HHS for transmission through the General Services Administration. (The Report includes information on activities, all costs for the year, membership, workload, site visits, and staffing);
- Prepare the Annual Report to the Secretary, including rosters and minutes of every meeting of the SEP, with a copy to the Library of Congress for public inspection and use;
- Prepare the annual Public Health Service Report, including functions of each committee, all meeting dates for the calendar year, and membership rosters;
- Prepare the annual Committee Balance Report to HHS in the aggregate by SEP, including distribution of reviewers by gender, minority status, geographic balance, and frequency with which reviewers were used:
- Maintain official file of the SEP.

Rev 02/00

17 - SIGN-IN SHEET (For Non-Research ONLY)*

Sign-In Sheet

A sign-in sheet of all members who served on the panel MUST be submitted for each SEP meeting and should be attached to the meeting minutes. The FACMT will enter the information from the roster into a database of SEP members.

Example of "Conflict of Interest and Sign-in Sheet"

Centers for Disease Control and Prevention Conflict of Interest and Confidentiality of Information

| Conflict of Interest and Confidentiality of Information | | | |
|---|--|--|--|
| The Disease, Disability, and Injury Prevention and | Control Special Emphasis Panel: | | |
| | | | |
| Meeting Date(s): | | | |
| This will certify that in the review identified above grant or cooperative agreement application from: I system in which a financial interest exists to myse investigators; 2) any organizations in which I serve collaborating investigator; or 3) any organization varrangements concerning prospective or other such | I) any organization, institution, or university lf, my spouse, parent, child, or collaborating e as officer, director, trustee, employee, or with which I am negotiating or have any | | |
| Moreover, I fully understand the confidential natural discussions related thereto and agree: 1) to destroy to discuss these materials and the review proceeding. Federal Official; and 3) to refer all inquiries made proceedings to the Designated Federal Official. | or return all review-related materials; 2) not ngs with any individual except the Designated | | |
| (Printed Name) | (Signature) | | |
| | | | |
| | | | |
| | | | |

st For peer review use the sign-in form generated by IMPAC II

http://intraspn.cdc.gov/maso/EForms/PDF/01215C.pdf

18 – ROSTER*

A Roster of all members who served on the panel must be submitted for each SEP meeting and should be attached to the meeting minutes. The FACMT will enter the information from the roster into a database of SEP members.

The roster may be in any format convenient to the program (e.g., list, table) <u>as long as all of the following information is furnished:</u>

Panel Member's name and degrees

Title (in organization)

Department (in organization)

Organization name

Organization address

Organization city/state/zip

Phone number

FAX number

E-mail address

Please attach to sign-in sheet and minutes when forwarding to FACMT.

*For peer review use the roster generated in IMPAC II

19 - PANEL MEETING MINUTES

The DFO ensures detailed minutes are kept Minutes will contain:

- Dates and times of meeting
- Location of meeting
- Membership roster
- Names of others in attendance
- Signatures of Panel Chairperson and DFO, certifying accuracy
- Total number and types of grants reviewed
- Total dollars requested
- Total number of applications and dollar amounts favorably recommended
- Total number of applications and dollar amounts not recommended for further consideration
- Total number of applications and dollar amounts recommended for deferral

The original signed minutes will be filed in the official meeting file in the Committee Management Office. The minutes and roster are due within 14 days following the review.

Please use the follow form to submit your minutes:

http://intraspn.cdc.gov/maso/EForms/PDF/Form1681.pdf

20 - MEMBER COMPENSATION

- Travel for SEP members will be processed by the program office sponsoring the SEP. (if the Meeting Support contract is used, the contractor will process the travel using the automated travel system for Federal employees, and if requested will use a private vendor for the non-Federal reviewers. This is the program's choice and must be made as part of the Statement of Work.)
- Members outside the Federal government may be compensated at the rate of no more that \$250 per day. (does not include travel time)
- Twenty-one days prior to the meeting, the DFO will submit a requisition through their Administrative Office for a purchase order to compensate panel members*for professional services. (if the Meeting Support contract is used, the contractor will compensate the panel members)

Justification

| ecommendations at the (name of SEP) | | | |
|-------------------------------------|----------------------|--|--|
| | | | |
| be held (date) | at (location of SEP) | | |

^{*}List the name, address, and Social Security Number of each panel member to be compensated at the \$250 daily rate.

21 - COMPENSATION REPORT

Within 45 days after the close of the meeting, the DFO/CIO should submit a completed Compensation Report (CDC 0.1216) to the FACMT.

The following information is needed to complete the report:

- Name of Special Emphasis Panel (SEP)
- Date(s) of SEP
- Total Number of Panel Members (report total Federal members and total non-Federal members)
- Number of Panel Members Paid (not all members accept compensation)
- Total Number of Days for Which Paid
- Total Amount Paid
- Travel and Per Diem Payments
- Non-Federal Panel Members (amount paid)
- Federal Panel Members (amount paid)
- Federal Staff (amount paid)

Amount paid to members serving on CDC and ATSDR Federal Advisory Committees = \$250 per day.

The completed form should be returned within 45 days to: Federal Advisory Committee Management Team, MASO Attn: SEP Team, Executive Park 22, MS-E72.

Rev. 11/00

EXAMPLE COMPENSATION REPORT

Centers for Disease Control and Prevention Special Emphasis Panel Compensation Report

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP) (insert meeting name and SEP #)

| Date(s) of SEP: | Total # of Panel Members | (including chair) | |
|---------------------------|---------------------------------------|--------------------|--|
| | Total # of non-Federal Panel Members: | | |
| # of Panel Members Paid*: | Total # of | Total Amount Paid: | |
| | Days Paid**: | \$ | |

**Total number of days equals the Total Number of Panel Members X Total Number of Meeting

Days

Amount paid to members serving on CDC and ATSDR Federal Advisory Committees = \$250 per day. Members are paid for any days the whole group convenes, including portions of the day (i.e., Orientation Session the night before the actual review).

Travel and Per Diem Payments

| Non-Federal Panel Members | Federal Panel Members | Federal Staff |
|---------------------------|-----------------------|---------------|
| \$ | \$ | \$ |

CDC 0.1216 Rev. 2/00

^{*}All members do not accept compensation.

22 - OFFICIAL FILE

The Federal Advisory Committee Management Team (FACMT), MASO, will maintain the Official File for all SEP meetings.

Official File Checklist

- Federal Register Notice
- Determination to Close the Meeting
- Appointment Memo, and Appointment Memos and Waivers if applicable
- Conflict of Interest Forms Originals (Signed prior to SEP meeting) (CDC Form 1215a)
- Conflict of Interest and Confidentiality of Information (Signed at the SEP Meeting) (CDC Form 1215b)
- Meeting Roster (CDC Form 1215b)
- Agenda (for public distribution)
- Compensation Report (CDC Form 1216)
- Official Minutes of Meeting (Signed by Chairperson and DFO)

Rev 2/00

23 - CHARTER FOR THE DISEASE, DISABILITY, AND INJURY PREVENTION AND CONTROL SPECIAL EMPHASIS PANEL

Purpose

The Secretary of Health and Human Services is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) to make grants-in-aid for research projects relating to health. In addition, the Secretary is authorized under Sections 306, 308, 317, 317A, 318, 391, 1501, 1701, and 1706 of the Public Health Service Act (42 U.S.C. 242k, 242m, 247b, 247b-1, 247c, 280b, 300k, 300u, 300u-5); Section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9604(i)); and other authorities as appropriate to support grants, cooperative agreements, and studies relating to the prevention and control of diseases, disabilities, injuries, and impairments of public health significance.

This panel will review applications and proposals for research projects and for grants and cooperative agreements in the areas of the causes, prevention, and control of diseases, disabilities, injuries, and impairments of public health significance; exposure to hazardous substances in the environment; health promotion and education; and other related activities that promote health and well-being.

Authority

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Panel is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

Function

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel shall provide advice and guidance to the Secretary; Health and Human Services; the Director, Centers for Disease Control and Prevention; and the Administrator, Agency for Toxic Substances and Disease Registry, regarding the scientific and technical merit of grant and cooperative agreement assistance applications relating to the causes, prevention, and control of diseases, disabilities, injuries, and impairments of public health significance; exposure to hazardous substances in the environment; health promotion and education; and other related activities that promote health and well-being.

Structure

Members and Chairs shall be selected by the Secretary, or other official to whom the authority has been delegated, on an "as needed" basis in response to specific applications to be reviewed. The Panel will consist of approximately 1200 members, of whom approximately 300 may be voting ex officio members. Members will be selected from authorities in the various fields of prevention and control of diseases, disabilities, and injuries. Members of other chartered Department of Health and Human Services' advisory committees may serve on the Panel if their expertise is required.

Management and support services shall be provided by the Federal Advisory Committee Management Team, Centers for Disease Control and Prevention.

Meetings

Meetings shall be held as necessary (approximately 40 times per year) as determined by the Designated Federal Official, who shall also approve the agenda. A government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated; notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

Compensation

Members who are not full-time Federal employees shall be paid at the rate of up to \$250 per day, plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

Estimated annual cost for operating the Panel, including compensation and travel expenses for members but excluding staff support, is \$825,000. Estimate of annual person-years of staff support required is 2.1 at an estimated annual cost of \$155,704.

Reports

In the event a portion of a meeting is closed to the public, a report shall be prepared annually which shall contain, at a minimum, a list of members and their business addresses; the Panel's function, dates and places of meetings; and a summary of panel activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel will terminate on September 18, 2006.

APPROVED:

(Signed and dated August 19, 2004, by the Director, Management Analysis and Services Office)

24 - IMPORTANT LINKS:

FEDERAL ADVISORY COMMITTEE ACT (FACA)

http://intranet.cdc.gov/maso/cmppa/pdfs/faca.pdf

GOVERNMENT IN THE SUNSHINE ACT

http://intranet.cdc.gov/maso/cmppa/pdfs/sunshineact.pdf

DELEGATIONS OF AUTHORITY

http://intranet.cdc.gov/maso/cmppa/doa.htm

AWARDING AGENCY GRANTS ADMINISTRATION MANUAL (AAGAM):

http://intranet.grantsinfo.hhs.gov

Scroll down to the 'HHS Grant Policies' section and click on 'Awarding Agency Grants Admin. Manual'

FINAL RULE

http://intranet.cdc.gov/maso/cmppa/pdfs/FR-FACA.pdf

GENERAL ADMINISTRATION MANUAL (GAM9)

http://intranet.cdc.gov/maso/cmppa/pdfs/gam9.pdf